

REMARKS

This Amendment is in response to the Office Action mailed June 16, 2004, having a three (3) month shortened statutory period for reply. A Petition for a Three Month Extension of Time in accordance with 37 C.F.R. §§1.136(a) and 1.17(a) is submitted herewith.

Claims 1, 2 and 11-19 are pending and claims 3-10 are cancelled in this application.

No new matter has been added to the claims or specification by the amendment. Support for all amendments are found in the originally filed claims and specification.

Attached herewith is a Supplemental Information Disclosure Statement Under 37 C.F.R. § 1.97(b).

Applicant requests consideration and entry into the record of the following amendments and remarks.

Supplemental Information Disclosure Statement(s)

For the record, applicants point out that an inadvertent error was made on the PTO 1449 Form attached with the Information Disclosure Statement Filed on October 22, 2004. In particular, the U.S. Patent Document identified therein as U.S. Appln. Serial No. 10/031,844 (GSK Internal No. P32372) refers to the above-identified application of the present response.

In light of this, applicants submit herewith a Supplemental Information Disclosure Statement to correctly identify reference to co-pending related subject matter of U.S. Appln. Serial No. 10/031,768, now refiled as a continuation of U.S. Appln. Serial No. 10/720,788 (P32371).

Rejection Under 35 U.S.C. §132 (New Matter)

Specific terms or phrases (identified below) introduced into the specification by the March 29, 2004 Amendment are rejected as new matter for lacking support in the originally filed specification.

Applicants respectfully disagree with the specific terms or phrases identified by the Examiner as new matter and traverse for reasons below.

Each of the new matter terms identified as lacking support by the Examiner and applicants' corresponding response arguments are set forth below.

[1] The Examiner maintains that new matter was introduced by recitation of the term "optionally substituted C1-4alkyl" as reflected by amendment to page 2, lines 34-37 to page 3, lines 1-8, which recites:

"C1-4 alkyl optionally substituted or ethenyl substituted with any of the substituents listed above for R3 and up to 3 groups R12 independently selected from . . .";

Applicants point out that no new matter has been introduced into the instant specification as support for the term "optionally substituted C1-4alkyl" is found in the specification at page 6, line 4, which recites:

"Preferred examples of R3 include hydrogen, optionally substituted aminocarbonyl; **optionally substituted (C1-6)alkyl . . .**"

Also, see page 11, line 10-13 of the March 29, 2004 Amendment, also which shows support for the fact that the above-identified term is found in the specification at page 6, line 4.

[2] The Examiner further indicates that the specification does not support the new matter term "R¹² as defined in R³", which was introduced by an amendment at page 4, lines 11-19.

Applicants maintain that no new matter has been added with recitation of the phrase "R¹² as defined in R³".

In particular, the phrase "R¹² as defined in R³" simply clarifies that the group of substituents associated with the functional group substituent R¹² is defined within the definition of the R³ functional substituent group. Support for this amendment is found throughout the originally filed disclosure or specification, for example: [1] see the specification definition of R³ substituents at page 2, lines 33 to 37 to page 3, lines 1 to 24, where the term R¹² is defined within the definition of R3 as noted on lines 8 to 24 of page 3; [2] originally filed claim 1, which is part of the originally filed disclosure; see claim 1 at page 33, lines 28 to 37 to page 34, lines 1-7; and [3] further clarification was provided in amended claim 1 of the March 29, 2004 Amendment under the Listing of Claims at page 5, line 28, which recites within the definition of R3, the phrase "up to 3 groups for R¹² . . ."

For example, applicants note that the term "R¹² as defined in R³" further clarifies possible substitution for functional group terms "amino" or "aminocarbonyl" as associated with each of the functional groups R⁶, R⁷, R⁸, and R⁹. Moreover, substitution of an amino or aminocarbonyl group as defined in the R³ definition is within the R¹² definition as the R³ group cannot itself be an (optionally substituted) amino or aminocarbonyl moiety.

Rejection Under 35 U.S.C. §112, 1st and 2nd paragraphs

Claims 1-2 and 11-19 are rejected under 35 U.S.C. §112, 1st para., for failure to comply with the written description requirement as claims contain subject matter not

described in the specification to reasonably convey to one skilled in the art that the inventor at the time the application was filed had possession of the claims invention.

Applicants respectfully disagree and traverse the above-identified rejections.

Each of the terms that the Examiner indicated lacks support and applicants' response arguments are set forth below.

[1] The Examiner states that the term "N-oxide" or N-oxide derivative" lacks support in the specification and that the phrase "salt, ester and/or N-oxide derivative" in claims 1, 17 and 18 is deemed new matter.

Applicants respectfully disagree that the term "N-oxide" or N-oxide derivative" lacks support and that the statement "salt, ester and/or N-oxide derivative" is new matter.

Applicants reiterate that the term "N-oxide" or N-oxide derivative" is supported by the specification at page 8, lines 24, which states (see also March 29, 2004 Amendment at page 11, lines 3 to 4):

"Compounds of formula (I) may also be prepared as the corresponding N-oxides".

In light of the foregoing, there is no new matter recitation set forth in the corresponding phrase "salt, ester and/or N-oxide derivative".

However, in the interest of advancing prosecution, applicants have amended claims 1, 17 and 18 to delete the terms "ester" and "derivative". Newly amended claims 1, 17 and 18 now recite "A compound of formula (I) or a pharmaceutically acceptable salt or N-oxide thereof".

[2] The Examiner has rejected the term "N-substituted" as it relates to the phrase "N-substituted $\text{CHR}_{13}\text{CONH}_2$ " as new matter.

Applicants have overcome this rejection by deletion of the term "N-substituted" with claim 1 now reciting original claim language as supported by the originally filed disclosure as follows:

"additionally when Z^5 is . . . $\text{CH}(\text{R}^{13})\text{CONH}_2$ optionally further substituted by (C_{1-6}) alkyl, hydroxy (C_{1-6}) alkyl, aminocarbonyl (C_{1-6}) alkyl or (C_{2-6}) alkenyl; hydroxy (C_{1-6}) alkyl; carboxy; cyano or (C_{1-6}) alkoxycarbonyl . . ."

[3] The Examiner states that insertion of a new paragraph with optional substituents at the end of R^3 definition lacks support in the specification and is new matter.;

Applicants point out that no new matter appears in amended claim 1, which now defines specific substituent groups that are optionally substitutable on specifically defined aryl

substituent groups (i.e., phenyl, benzoyl, heteroaryl and heteroaroyl groups) defined within the definitions of R³ and R⁵ moieties.

Specific support for the substitution of the aforementioned aryl groups from the previously made claim amendment appears at page 7, lines 12-16 of the instant specification:

“Aryl groups, e.g., phenyl and benzoyl; heteroaryl and heteroaroyl groups may be optionally substituted with up to five groups selected from halogen, mercapto, (C₁₋₆)alkyl, phenyl, (C₁₋₆)alkoxy, hydroxy(C₁₋₆)alkyl, mercapto (C₁₋₆)alkyl, halo(C₁₋₆)alkyl, hydroxy, optionally substituted amino, nitro, carboxy, (C₁₋₆)alkylcarbonyloxy, (C₁₋₆)alkoxycarbonyl, formyl, and (C₁₋₆)alkylcarbonyl groups.”

[4] The Examiner states that recitation of the term “R¹² as defined in R³” lacks support in the specification and is new matter”

Applicants have obviated the new matter rejection as support from the specification has been shown for the use of the term “R¹² as defined in R³” *supra* under the section identified as Rejection Under 35 U.S.C. §132, New Matter.

Claims 1-2 and 11-19 are rejected under 35 U.S.C. §112, 2nd para., for being indefinite and for failing to particularly point out and distinctly claim the invention.

The Examiner states that the term “ester” as recited in amended claims 1, 17 and 18 renders those claims indefinite as it is unclear what such esters are or what the difference is between the claimed esters and those included in the definitions of variable groups.

As indicated above, applicants have overcome this rejection by amending claims 1, 17 and 18 to delete the term “ester”.

In each of the above-identified amendments, no new matter has been added to the claims of the present application and support from the specification for those amendments also have been identified.

In light of the above, applicant requests that the above rejection under 35 U.S.C. § 112, 1st and 2nd paragraphs, be withdrawn.

Claim Objections

Claims 1, 2 and 11-19 are objected to for inclusion of non-elected subject matter.

Applicants have overcome this rejection by amending claim 1 to reflect elected Group III, wherein one of Z¹, Z², and Z³ is N, and Z⁴, Z⁵ and remainder of Z¹, Z², and Z³ not equal to N are CR^{1a};

In light of this, applicants request that the above-identified claim objections be withdrawn and that the claims now are in condition for allowance.

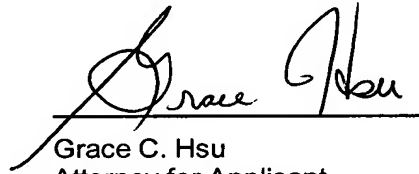
CONCLUSION

In view of the above amendments and remarks, applicant believes that the claims of the present application are in condition for allowance and is earnestly solicited .

If any additional fees or charges are required authorization is hereby granted to charge any necessary fees to Deposit Account No. 19-2570 accordingly.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Grace C. Hsu", is written over a horizontal line.

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